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IPW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

THE APPLICATION

OF: WITTELER ET AL.

SERIAL NO. 10/070,758

FILED: MARCH 12, 2002

FOR: PROCESS FOR PREPARATION OF POLYVINYLPYRROLIDONE-IODINE IN AQUEOUS SOLUTION

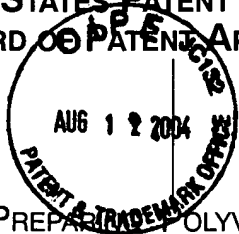
TO: HON. COMMISSIONER OF PATENTS AND TRADEMARKS

MAIL STOP: APPEAL BRIEF

CONFIRMATION NO.: 2769

GROUP ART UNIT: 1615

EXAMINER: B. M. FUBARA



I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner of Patents and Trademarks, Alexandria, Va 22313-1450, on:

August 12, 2004

Date of Deposit

Karen Stamper

Person Making Deposit

Signature

August 12, 2004

Date of Signature

Sir:

1. ☐ NOTICE OF APPEAL: Applicant hereby appeals to the Board of Appeals from the decision dated -/-, of the Primary Examiner finally rejecting Claims -/-.
2. ☒ Applicants hereby petition for a -1- month extension of time under 37 C.F.R. §1.136. Applicants request entry of their timely reply dated April 30, 2004, for purposes of appeal.
 - ☒ A check to cover the fee of -\$110.00- is enclosed.
 - ☐ A petition for a -/- month extension of time including the requisite fee of -/- has been filed along with the amendment under 37 C.F.R. §1.116 dated -/-.
3. ☒ BRIEF ON APPEAL in this application is transmitted herewith.
4. ☐ An oral Hearing is requested
 - ☐ The Oral Hearing fee of -/- is enclosed.
5. ☒ Fee \$330.00 + \$110.00 = \$440.00
 - ☒ Enclosed.
 - ☐ Not required (Fee paid in prior appeal).
 - ☐ Charge to Deposit Account No. 11.0345.
6. ☒ The Commissioner is hereby authorized to charge any fee which may be further required, or credit any over payment to Deposit Account No. 11.0345. A duplicate copy of this sheet is attached.

Respectfully submitted,

KEIL & WEINKAUF

Daniel S. Kim

Daniel S. Kim

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
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RE APPLICATION

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August 12, 2004

Honorable Commissioner

for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Date of Deposit Karen Stamper

Person Making Deposit

Signature

August 12, 2004

Date of Signature

BRIEF ON APPEAL UNDER 37 C.F.R. §1.192

Sir:

This is an appeal from the Examiner's final rejection of Claims 1 to 9 and 12, dated February 13, 2004. Claims 1 to 9 and 12 are currently pending.

REAL PARTY IN INTEREST:

The real party in interest is BASF Aktiengesellschaft, 67056 Ludwigshafen, Germany.

RELATED APPEALS AND INTERFERENCES:

To the best of the undersigned's knowledge, there are no related appeals or interferences within the meaning of 37 C.F.R. §1.192(c)(2).

STATUS OF THE CLAIMS:

The claims on appeal before the Board of Patent Appeals and Interferences are Claims 1 to 9 and 12. A copy of these claims is found in the attached Appendix.

STATUS OF THE AMENDMENTS:

The application has not been amended after final rejection. Prior to final rejection, Claims 3 to 8, 10 and 12 were amended to elimi-

nate multiple dependency and to place them in better form¹⁾, the dependency of Claim 4 was revised and Claims 10 and 11 were canceled²⁾.

SUMMARY OF THE INVENTION:

Appellants' invention relates to a process for preparing polyvinylpyrrolidone-iodine (PVP-iodine) wherein polyvinylpyrrolidone (PVP) is reacted with elemental iodine in aqueous solution, and to products obtained by that process³⁾. In accordance with appellants' process it is *inter alia* required that the PVP is employed in the aqueous solution in a concentration which is higher than a particular minimum concentration where the minimum concentration is a function of the K value⁴⁾ of the PVP which is employed in the process. More specifically, appellants have found that the aqueous PVP solution which is employed in the process has to have a PVP concentration c, in % by weight, relative to the K value of of the PVP, which obeys the relation⁵⁾:

$$c > 100 \times [0.1 + 8 : (K + 5)]$$

Appellants have further found that the combination of requirements which characterizes the process defined in Claim 1 accelerate the formation of PVP-iodine, cf. the reaction times in appellants' process are shorter than the reaction times of a process which uses a PVP solution wherein the PVP concentration is lower than the minimum concentration⁶⁾. Appellants have also found that the PVP-iodine which is formed under the conditions of their process exhibits a markedly improved stability⁷⁾.

ISSUE(S) PRESENTED:

Whether the Examiner erred finding that the subject matter of

- 1) Preliminary Amendment submitted upon filing of the application.
- 2) Reply dated October 31, 2003 (*date of the Certificate of Mailing*).
- 3) Appellants' process is defined in Claim 1 and further specified in Claims 2 to 7, and is incorporated into Claims 8, 9 and 12 by reference.
- 4) The K value is a measure of the molecular weight of the polyvinylpyrrolidone and is determined as described by H. Fikentscher, *Cellulose-Chemie*, 13, 58-64 and 71-74 (1932) as 1% by weight solution in water. See for example page 3, indicated lines 41 to 44, of the application.
- 5) The minimum concentration c_{\min} which is to be surpassed in accordance with appellants' process is, correspondingly, equal to $100 \times [0.1 + 8 : (K + 5)]$.
- 6) Note page 2, indicated line 34 et seq., and the data in Table 1, page 24, of the application.
- 7) Note page 2, indicated line 28 et seq., and the data in Table 1, page 24, of the application.

appellants' Claims 1 to 9 and 12 is anticipated under 35 U.S.C. §102(b) by the teaching of *Denzinger et al.* (US 4,402,937).

GROUPING OF THE CLAIMS:

For the issue(s) above it is affirmed that Claims 2 to 9 and 12 stand and fall with Claim 1.

ARGUMENTS:

For the following reasons, the Examiner's finding that the teaching of *Denzinger et al.* anticipates the subject matter of appellants' Claims 1 to 9 and 12 within the meaning of 35 U.S.C. §102(b) is deemed to be in error.

The teaching of *Denzinger et al.*⁸⁾ relates -like appellants' invention- to a process for the preparation of PVP-iodine by reacting PVP and elemental iodine in aqueous solution. The Examiner takes the position that the teaching of *Denzinger et al.* meets all limitations of appellants' claims because⁹⁾ of

- the disclosure in col. 3, indicated lines 37 to 41, of *US 4,402,937*, that PVP having a K value of from 8 to 50 can be employed; and
- the disclosure in col. 4, indicated lines 33 to 37, of *US 4,402,937*, that the PVP can be employed in concentrations of from 10 to 60% by weight.

The Examiner acknowledges in this context that the examples disclosed by *Denzinger et al.* are merely illustrative of some combinations of K values and PVP concentrations and do not cover all of the combinations of K values and PVP concentrations which are possible within the ranges addressed in the generic description provided by *Denzinger et al.*¹⁰⁾.

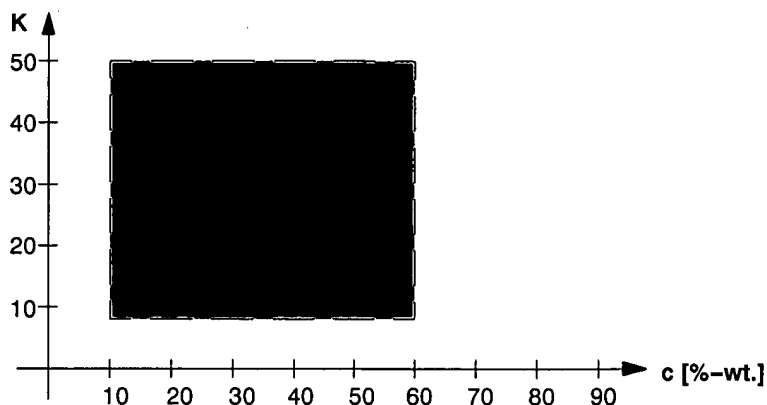
The Examiner's position that *Denzinger et al.*'s disclosure allows for a combination of any one of the K values and and any one of the PVP concentrations which falls within the ranges of K values and of PVP concentrations taught by *Denzinger et al.*, cf. all com-

8) The European equivalent of *Denzinger et al.*'s U.S. patent, EP 027 613, is addressed in the paragraph on page 2, indicated lines 15 to 26, of the application.

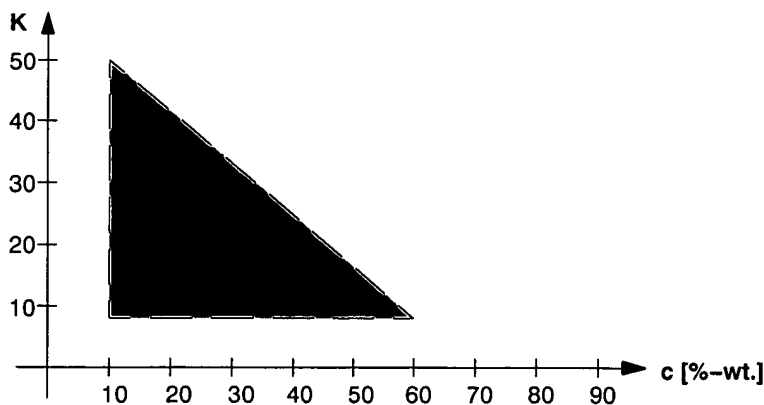
9) Ie. page 3, lines 2 to 4 and line 13, of the final action.

10) Ie. page 3, lines 10 to 13, of the final action.

binations which fall within the shaded area in the following graphical representation:



is not deemed to be well taken. *Denzinger et al.* clearly state that the higher concentrations apply to PVP having a low K value, and vice versa¹¹⁾. Areas of the foregoing square which represent solutions comprising a PVP with a low K value in a low concentration, or solutions comprising a PVP with a high K value in a high concentration, are therefore not encompassed by the generic teaching of *Denzinger et al.* In light of *Denzinger et al.*'s statement, the area which represents all combinations of PVP concentration and PVP K value which are encompassed by the generic teaching of *Denzinger et al.* cannot reasonably be deemed to extend beyond the following shaded triangle:



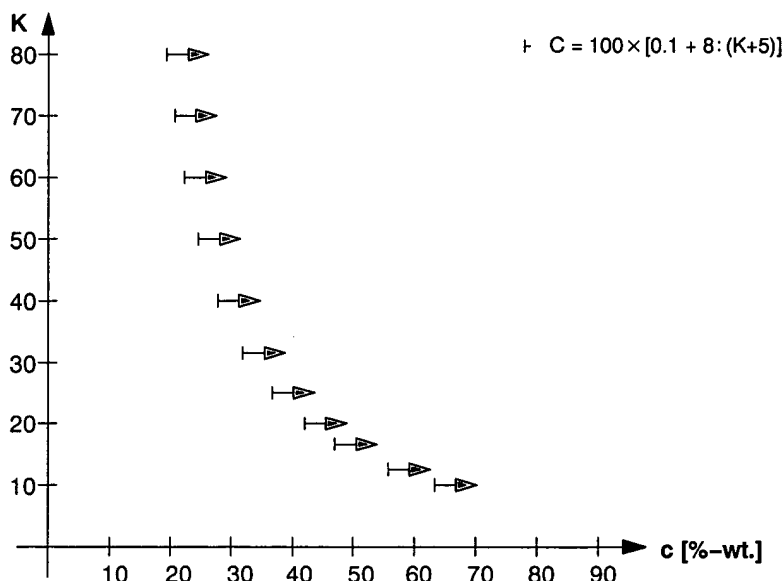
The Examiner position that the generic teaching of *Denzinger et al.* is sufficient to anticipate all possible combinations of any one of the concentrations and any one of the K values which fall within

11) Col. 4, indicated lines 35 to 37, of *US 4,402,937*. The statement of *Denzinger et al.* reflects the general technical background knowledge that, at the same concentration, a solution of a PVP having a high K value is more viscous than a solution of a PVP having a low K value. Accordingly, when solutions of identical viscosity are prepared from two PVPs having different K values, the concentration of the solution containing the PVP with the lower K value is higher than the concentration of the solution containing the PVP with the higher K value.

the generic ranges for the PVP concentration and for the K value of the PVP is not deemed to be well taken. A generic disclosure is not sufficient to anticipate each species or subgenus which happens to fall within the generic range of the disclosure¹²⁾. To anticipate a claimed invention within the meaning of Section 102, a reference has to show exactly what is claimed, cf. the identical subject matter has to be shown in the reference in as complete detail as is contained in the claim¹³⁾. The information which is provided by *Denzinger et al.* in cols. 3 and 4 of **US 4,402,937** concerning ranges of K values and ranges of PVP concentrations cannot reasonably be deemed to show exactly an aqueous solution wherein the PVP concentration and the K value of the PVP obey the relation:

$$c > 100 \times [0.1 + 8 : (K + 5)]$$

cf. a combination of a PVP concentration and a PVP K value which falls within the area above and to the right of a line connecting the arrows in the following illustration:



Apart from the information that PVPs having a high K value are employed at low concentrations and vice versa, the generic teaching of *Denzinger et al.* does not contain information which allows the

12) Note in particular Corning Glass Works v. Sumitomo Electric U.S.A., 868 F.2d 1251, 9 USPQ2d 1962 (CAFC 1989), and Minesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 24 USPQ2d 1321 (CAFC 1992), which emphasize that a genus does not inherently disclose all species; and also In re Jones, 958 F.3d 347, 21 USPQ2d 1614 (CAFC 1992), and In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (CAFC 1994), which point out that a genus does not even render all species that happen to fall within the genus obvious.

13) Richardson v. Suzuki Motor Co., 868 F.2d 1226, 9 USPQ2d 1913 (CAFC 1989); Lindemann Maschinenfabrik v. American Hoist & Derrick Co., 730 F.2d 1452, 221 USPQ 481 (CAFC 1984).

determination of a particular correlation between the PVP concentration in the solution and the K value of the dissolved PVP. Such a particular correlation between the PVP concentration in the solution and the K value of the dissolved PVP is only possible based on the examples illustrating *Denzinger et al.*'s generic teaching. In the illustrative examples, *Denzinger et al.* employ the following aqueous PVP solutions:

- (A) A 30% by weight aqueous solution of a PVP having a K value of 31.5 in Example 1¹⁴).

Appellants' process as defined in Claim 1 requires that a PVP having a K value of 31.5 be employed in a concentration of more than 31.9% by weight¹⁵).

- (B) A 40% by weight aqueous solution of a PVP having a K value of 16.5 or 17 in Examples 2, 4 and 5a to 5c¹⁵).

Appellants' process as defined in Claim 1 requires that a PVP having a K value of 16.5 be employed in a concentration of more than 47% by weight, and that a PVP having a K value of 17 be employed in a concentration of more than 46.4% by weight¹⁶).

- (C) A 50% by weight aqueous solution of a PVP having a K value of 12.5 in Example 3¹⁵).

Appellants' process as defined in Claim 1 requires that a PVP having a K value of 12.5 be employed in a concentration of more than 55.7% by weight¹⁶).

The foregoing shows that none of the examples which are disclosed by *Denzinger et al.* meets appellants' requirement that the PVP be employed in a concentration c which is in the relation to the K value expressed by

$$c > 100 \times [0.1 + 8 : (K + 5)]$$

Denzinger et al.'s examples therefore also fail to show exactly what is defined in appellants' Claim 1.

Since neither the generic teaching of *Denzinger et al.* nor the illustrative representative examples of *Denzinger et al.* show exactly what is claimed in appellants' Claim 1, the teaching of *Denzinger et*

14) The more detailed remarks on the solutions employed by *Denzinger et al.* which are set forth on pages 3 to 4 of appellants' Paper No. 07, dated October 31, 2003, which is herein incorporated by reference.

15) The respective calculations are set forth on pages 4 and 5 of appellants' Paper No. 09, dated April 30, 2004, which is herein incorporated by reference.

al. in US 4,402,937 cannot be deemed to anticipate appellants' process within the meaning of Section 102.

The Examiner has criticized that appellants have failed to claim a K value which is categorically linked with a specific concentration of the PVP solution¹⁶). Appellants' invention does not involve that a PVP having a particular K value has to be employed in the process in one specific concentration and the Examiner's respective criticism is therefore not deemed to be well taken.

In the advisory action, the Examiner has also remarked that appellants' requirement " $c > 100 \times [0.1 + 8 : (K + 5)]$ " gives rise to the question "How much larger?"¹⁷). This criticism was raised by the Examiner for the first time in the advisory action and is not deemed to be part of the final rejection in light of the provisions of Rule 113(b).

C O N C L U S I O N

For the foregoing reasons, appellants respectfully urge that the Examiner erred finding that appellants' invention defined in Claims 1 to 9 and 12 is anticipated by the teaching of *Denzinger et al.* It is respectfully requested that the Examiner's rejection of appellants' Claims 1 to 9 and 12 under 35 U.S.C. §102(b) be reversed.

REQUEST FOR EXTENSION OF TIME:

A petition for a one month extension of time is included in appellants' cover letter accompanying this appeal brief. A check covering the \$110.00 fee is attached.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees, to Deposit

16) For example advisory action dated May 17, 2004, page 2, and final action dated February 13, 2004, page 5, lines 11 to 13.

17) Advisory action dated May 17, 2004, page 2, lines 3 and 4.

Serial No. 10/070,758

WITTELER et al.

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Account No. 11.0345. Please credit any excess fees to such deposit account.

Respectfully submitted,

KEIL & WEINKAUF

A handwritten signature in cursive script, appearing to read "Dan Kim".

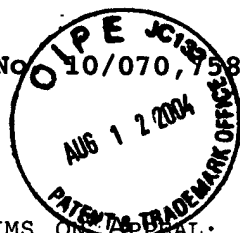
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Encl.: THE CLAIMS ON APPEAL (Appendix I)

HBK/BAS



A P P E N D I X I:

THE CLAIMS ON THIS PATENT:

1. A process for preparing polyvinylpyrrolidone-iodine in aqueous solution, where an aqueous polyvinylpyrrolidone solution and at least 4.0% by weight of elemental iodine, based on the polyvinylpyrrolidone calculated as solid, are mixed, wherein at the time of mixing the concentration c of the aqueous polyvinylpyrrolidone, based on the total amount of polyvinylpyrrolidone and water, and the K value of polyvinylpyrrolidone obeys the following relation:
$$c > 100 \times [0.1 + 8 : (K + 5)]$$
where c is stated in % by weight, and the Fikentscher K value is in the range from 10 to 100.
2. A process as claimed in claim 1, wherein the mixture is heated at a temperature in the range from 50 to 110°C for a period of from 30 minutes to 15 hours.
3. A process as claimed in claim 1, wherein the mixing is carried out in the presence of a reducing agent.
4. A process as claimed claim 3, wherein the reducing agent is selected from formic acid, oxalic acid, the esters and salts of formic and oxalic acids, and the amides of carbonic acid, of formic acid and of oxalic acid.
5. A process as claimed in claim 1, wherein the polyvinylpyrrolidone solution and, where appropriate, at least part of the reducing agent are mixed, the mixture is heated where appropriate, and then iodine is added.
6. A process as claimed in claim 1, wherein a polyvinylpyrrolidone solution of a polyvinylpyrrolidone with a K value of > 27 and a polyvinylpyrrolidone content of $> 35\%$ by weight is employed.
7. A process as claimed in claim 1, wherein the polyvinylpyrrolidone-iodine present in the solution has an available iodine content of at least 4% by weight.
8. A polyvinylpyrrolidone-iodine solution obtainable by a process as claimed in claim 1.

9. A solid polyvinylpyrrolidone-iodine obtainable by removing the water and other volatile constituents from an aqueous polyvinylpyrrolidone-iodine solution as defined in claim 8.
12. An antiseptic composition comprising an aqueous polyvinylpyrrolidone-iodine solution as defined in claim 8 or solid polyvinylpyrrolidone-iodine obtainable by removing the water and other volatile constituents from an aqueous polyvinylpyrrolidone-iodine solution.